**IN THE UNITED STATES DISTRICT COURT**
**IN AND FOR THE NORTHERN DISTRICT OF GEORGIA**

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| ELIZABETH A. LAKEY, et al.,<br><br>Plaintiffs,<br><br>v.<br><br>MENTOR CORPORATION,<br><br>Defendant. | Civil Action No. 1:05-CV-0929-TCB |

**MENTOR CORPORATION'S MOTION TO EXCLUDE TESTIMONY OF PIERRE BLAIS, Ph.D. AND MEMORANDUM IN SUPPORT**

## INTRODUCTION

The testimony of Plaintiffs' proffered expert witness, Dr. Pierre Blais, does not meet the threshold standard for admissibility under Fed. R. Evid. 702. Indeed, by his own admission, Dr. Blais does not adhere to scientific methods and has refused to subject his work to the scrutiny of publication and peer review. Thus, not surprisingly, many courts have held that "the opinions expressed by Dr. Blais are not generally accepted in the scientific community . . ." Cabrera v. Cordis Corp., 945 F.Supp. 209, 214 (D. Nev. 1996) aff'd, 134 F.3d 1418 (1998). So, too, here.[1]

[1] Mentor has already moved for summary judgment on Plaintiffs' claims. (See Docket # 100). Mentor's motion for summary judgment should be granted irrespective of whether the Court grants this motion to exclude the testimony of Dr.

## FACTUAL BACKGROUND

### A. Dr. Blais' Background

According to his own testimony, Dr. Blais is a Canadian chemist. He has one post-graduate degree, a Ph.D. in chemistry. Blais is not a microbiologist, pathologist or a medical doctor. (Blais Dep. at 153, 162, 187, 226-27, relevant excerpts attached hereto as Exhibit A). He does not treat patients or diagnose disease. (Id. at 205-06). He does not convey warnings to patients. (Id.). Blais does not have an engineering degree and holds no engineering licensure in any jurisdiction. (Id. at 189-90). He has never worked for a medical device manufacturer. (Id. at 190). He has never designed a breast implant for use in a human being and has never submitted a breast implant design for a patent, to the FDA for approval, or to a medical device manufacturer for consideration. (Id. at 190-93).

Dr. Blais worked for the Canadian Government from 1968-1989. In 1989, Dr. Blais founded Innoval out of his home. In the 1990s, a significant portion of Dr. Blais' time was spent on, and a significant portion of his income was derived from, attempting to testify for plaintiffs in the silicone breast implant litigation.

(continued…)

Blais. If the Court does grant this motion to exclude, however, it is simply an additional reason why summary judgment is appropriate.

## B. Proffered Subjects of Testimony

Dr. Blais has issued a report in this matter which is 29 pages in length and, to a large extent, generic, consisting of a few pages of case-specific observations with the remainder comprised of various generic appendices (Blais Report dated August 26, 2004, attached hereto as Exhibit B).[2] Judge Sparr of the United States District Court for the District of Colorado, in excluding Dr. Blais from that breast implant litigation, noted that Dr. Blais' reports, in cut-and-paste fashion, "contain numerous statements about breast implants causing a variety of injuries" are "rife with conclusions about medical issues" and "cite some limited scientific literature to support his opinions." In Re Breast Implant Litigation, 11 F. Supp.2d 1217, 1241-42 (D. Col. 1998), attached hereto as Exhibit C.

In this case, for example, Dr. Blais' report states that some material in Plaintiff's left implant is "consistent with aspergilli and staphylococci sub-species." Dr. Blais testified, however, that he has not tested or identified the material and, if it is microbiological in origin, he does not know what kind of organism it is. (Blais Dep. at 148-49, 156, 213). This is not science, it is unqualified guesswork.

[2] As Judge Sparr observed, "Dr. Blais' reports appear to be written on forms with attached form appendices depending on the manufacturer and model of the implant." In Re Breast Implant Litigation, 11 F. Supp.2d at 1242.

Based on his report and deposition testimony, Dr. Blais, the all-purpose witness, will also apparently testify as to: (1) whether Plaintiff's implants contained a design defect; (2) whether Plaintiff's implants contained a manufacturing defect; (3) "all issues related to the tissue and implants removed from" Plaintiff; (4) injuries from bacterial or fungal colonization of breast implants; (5) and the history of Mentor's saline breast implants.

## C. Numerous Courts Have Excluded Dr. Blais' Testimony

Courts recognize that Dr. Blais is a zealot, not a scientist, who is willing to express opinions on a wide variety of issues well beyond his expertise and without any basis in accepted science. His reports and proposed testimony in this case follow the pattern discerned by other courts and, as those courts have held, his testimony should either be excluded in its entirety or extremely circumscribed.

### 1. Giddings v. Bristol-Myers Squibb Co., 192 F. Supp. 2d 421, 425 (D. Md. 2002), attached hereto as Exhibit D.

In this silicone gel breast implant case, the court granted the defendant's motion to exclude the testimony of Dr. Blais. In do doing, the court ruled,

> Based on the facts and circumstances of this case, the Court finds Dr. Blais unqualified to state an opinion on product defects. Dr. Blais is not a medical doctor. He is not a pathologist. He is not a toxicologist. By his own admission he is not qualified to diagnose medical conditions, provide treatment or give a prognosis for a patient. Yet the core of Dr. Blais' testimony is that the MEC breast implant is defective because it presents medical and toxicological risks. Finding

> that he lacks the basic skills, education and training of a medical doctor, toxicologist or pathologist to opine that the gel is harmful to the human body, the Court exercises its discretion to preclude his testimony.

The court went on, observing that Dr. Blais has not published any research or opinions in peer-reviewed literature. He proposed to testify in Giddings that the silicone gel used in those implants contained reactive impurities, but conceded that he had not done any testing to confirm the presence of the many harmful chemicals he alleged were present. The same is true here. Despite claiming that there is a tiny amount of something in Plaintiff's left implant that he believes is evidence of microbiological activity and causing Plaintiff harm, Blais has not done any testing to confirm what it is, nor does he think further testing will help.

**2. Pozefsky v. Baxter Healthcare Corp., No. 92-CV-0314, 2001 U.S. Dist. LEXIS 11813 (N.D.N.Y. Aug. 16, 2001), attached hereto as Exhibit E.**

In another silicone gel breast implant case, the court ruled that Dr. Blais' causation testimony was inadmissible. The court also noted that a number of federal, state and Canadian courts have excluded or strictly limited Dr. Blais' testimony in similar cases.

**3. Havard v. Baxter Int'l Inc., No. 1:92CV0863, 2000 U.S. Dist. LEXIS 21316 *22 (N.D. Ohio July 21, 2000), attached hereto as Exhibit F.**

The court excluded Dr. Blais's testimony regarding systemic diseases, the design or manufacturing of silicone breast implants, warnings associated with breast implants, or any other subject beyond his qualifications. The court was troubled by the fact that "Blais keeps no records, does not publish his opinions, and has not developed any relevant opinions independent of litigation." The court was also bothered that Innoval is based in Blais' home, possesses little equipment, and implants are stored in an annex "which may not be an environment that can preserve the implants adequately." Here, Plaintiff's implants have been stored for almost two years in that same annex in Blais' home.

**4. Grant v. Bristol-Myers Squibb, 97 F. Supp. 2d 986, 991 (D. Ariz. 2000), attached hereto as Exhibit G.**

The court excluded Blais' testimony, ruling "Blais may not testify as to any opinion he may have as to defects of breast implants or any other topic that is beyond his qualifications as a chemist." In so holding, the court observed that many other courts had found Blais' testimony on alleged defects in breast implants unreliable, and that he is not a medical doctor, has not supported his theories with testing and did not develop his opinions independent of litigation.

**5. In re: Breast Implant Litig., 11 F. Supp. 2d 1217, 1242-43 (D. Colo. 1998).**

In In Re Breast Implant Litigation, 11 F. Supp.2d 1217 (D. Col. 1998), the court excluded the testimony of Dr. Blais in its entirety in the silicone gel breast implant cases pending in that court. The opinion is comprehensive and worthy of extended quotation:

> Dr. Blais' hypotheses. . . have not been tested, nor have they been published in the peer reviewed literature. Neither Dr. Blais nor others have tested his theories. No publication of Dr. Blais' hypotheses, methodology or opinions exists in the peer reviewed literature. . . .
>
> Plaintiffs have not demonstrated that Dr. Blais' methodology or opinions are generally accepted in the scientific community.... The theories offered by Dr. Blais are not supported by generally accepted scientific data.
>
> Dr. Blais has not applied any definable scientific methodology, much less generally accepted methodology, to reach his opinions.
>
> Dr. Blais' opinions are not developed independent of litigation. In fact, the vast majority of Innoval's business comes from plaintiffs involved in breast implant litigation . . . This factor provides an additional reason for excluding Dr. Blais' testimony here.
>
> The Court concludes . . . that Dr. Blais is not qualified by knowledge, skill, experience, training, or education to testify about medical issues such as the presence of disease, the mechanism of disease, the causes of disease, or what occurs in the human body in response to the presence of a breast implant . . .
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> * * *
>
> As to his opinions concerning implant design, manufacturing, marketing, and labeling, Dr. Blais is a chemist with no experience in

> the design, manufacturing, marketing, or labeling of silicone breast implants and lacks the qualifications to opine about these subjects. . . . As a chemist, Dr. Blais is not automatically qualified to address the product liability issues of manufacturing, design, marketing, or labeling of silicone breast implants.
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> The Court finds that Dr. Blais' opinion testimony cannot survive the test of Rules 702, 703, Daubert, 509 U.S. at 579, or its progeny. . . . Dr. Blais' opinions do not meet the standards of scientific reliability that would permit them to be presented to the jury.

The court excluded the same type of testimony Dr. Blais would offer in this case, i.e., testimony regarding alleged manufacturing and design defects, medical issues related to breast implants, breast implant warnings, etc.

**6. New Mexico**

In Johnson v. Baxter Healthcare Corn., No. CV-92-07501 (Second Judicial District, County of Bernalillo, State of New Mexico, Feb. 23, 1998, attached hereto as Exhibit H), decided earlier the same year, Judge Schneider concluded that Dr. Blais would not be allowed to testify to anything beyond his physical observations of the implants. The Court explained:

> Dr. Blais is a troubling witness. Normally bias is a matter for the jury. Here, however, it appears that Dr. Blais is so biased it affects his objectivity and his ability to give an honest opinion. Notwithstanding this problem, Dr. Blais' theories as to breast implants in general are totally unscientific and therefore unreliable. He publishes nothing, keeps no set of systematic records of his tests or observations, and his opinions are peculiarly his own without any general acceptance in the scientific community and without any ability of testing or peer-review. Even if his testimony has some probative value, the prejudice

> to Defendants would outweigh that testimony. Any glib expert who has an opinion and nothing to support it can never be effectively cross-examined by an opponent, thus to allow such testimony would be prejudicial. He will not be allowed to give general opinions on the manufacture or design of implants, any immunological effects or responses, nor the issues of implant failure. Defendants concede that he may be able to testify as to his observations of the implants at issue, depending on the proffer. Accordingly, I am not deciding that issue at this time.

Johnson Opinion, at 4-5.

This decision again excludes the same testimony that Dr. Blais would offer here.

**7. British Columbia**

These recent decisions excluding Dr. Blais' testimony on grounds of personal bias and lack of scientific basis are not novel. Indeed, in Wilson v. Guichon, Supreme Court, British Columbia, Nos. C863922 (Aug. 7, 1990), appeal dismissed, 76 B.C.L.R. (2d), p. 191 (C.A.), Justice Hood made the following observations concerning Dr. Blais:

> . . . [I]t seems clear to me that in advancing his cause against the Meme implant, and in giving evidence at trial, Dr. Blais set aside the mantle of the scientist and replaced it with that of the zealot.... In many respects his evidence was not the objective and unbiased evidence which the Court expects of and requires from, a scientist, an expert. It was instead so obviously biased that in most respects it is of little value to the Court. His crusade and his methods used in

> attempting to discredit the Meme appear to have cost him his job.[3]... He was not responsive, he was not forthright, he exaggerated and was evasive. His misleading report which he well knew was to be placed in evidence in Court, and which he should have corrected immediately, is but one example of his overriding desire to stop the use of the Meme.

(Wilson Order, attached hereto as I).

**8. New York**

Judge Weinstein has also severely circumscribed the scope of Dr. Blais' testimony. In Clements v. 3M, (93-CV-5697, E.D.N.Y.) (Clements Hearing Transcript, attached hereto as Exhibit J), another local injury case, Judge Weinstein declared that, "I don't want him [Blais] to testify with respect to migration or systemic injuries or anything like that." (Clements Hearing at 85). The plaintiffs in that case also conceded that Blais would not be offering opinions "of the effect on

[3] Justice Hood's reference to Dr. Blais' loss of his job relates to Dr. Blais' discharge from his position with the Department of Health and Welfare, Canada. In a letter notifying him of his discharge, the Assistant Deputy Minister of the Department made the following observations:

> I am satisfied that you have conducted several serious infractions which place into question your scientific integrity and the element of trust and confidence which is essential to carry out your duties as a research scientist in the Bureau of Radiation and Medical Devices. . . . I am satisfied that you were involved in the unauthorized release of scientifically unsubstantiated material. . . . I find your actions in this regard to have been totally irresponsible, unprofessional and reprehensible in the context of your duties.

(Treasury Decision, attached as Exhibit K).

human tissue or the breast environment, that is out of his area." Informed that, "he wants to testify according to his report and offer opinions about the rate of implant removal, capsulotomies, procedure within the plastic surgery community --," the Court declared, "I don't want that." (Clements Hearing, at 87).

**9. Texas**

In Minnesota Mining and Manufacturing Co. v. Atterbury, 978 S.W.2d 183 (Tex. App. 1998, petition denied) the appellate court reconsidered the causation testimony of Dr. Blais. In overruling the motion for rehearing, the court stated:

> Although [Blais] was not designated to testify concerning causation, he was allowed, over vehement objection, to express some causation opinions. However, we find his testimony in this area unreliable under the Robinson/Havner criteria. As an organic chemist, he is a biomaterials expert and was not otherwise shown to be qualified to render an opinion on medical causation. He admitted to having no qualifications in medicine. His causation opinions have not been scientifically tested. Although he characterized those opinions as "objective," he provided no objective criteria of measurement to support them. The record does not show that his opinions have been peer reviewed as contemplated under the Robinson criteria, and they have not been generally accepted by the scientific community. Most of his opinions were developed in the context of litigation. For these reasons, we find Blais' causation testimony not reliable under the criteria established by the Texas Supreme Court.

Id. at 203, attached as Exhibit L. Likewise, the then-coordinating judge for all breast implant cases in Dallas County rejected Dr. Blais' testimony. Bailey v. Dow Corning Corporation. et al., 1996 WL 937659 (Tex. Dist. 1996), attached as

Exhibit M. In granting 3M's motion to exclude Dr. Blais, the court ruled that Dr. Blais' causation testimony is inadmissible pursuant to the standards outlined in Robinson. Id.

Finally, in Bonnette v. Minnesota Mining and Manufacturing Company, Cause No. 96-449 17, 129th Judicial District, Harris County, Texas, Judge Mizell struck Dr. Blais in his entirety, noting that "[t]he man is incapable — incapable of— and I don't mind saying this on the record. He's incapable of giving a responsive answer and he's incapable of not interjecting objections or if he's not interjecting opinion, as you all know.. . there has to be something that doesn't meet the eye." (Bonnette Hearing Transcript at 42, attached hereto as Exhibit N). Even as to Dr. Blais' non-causation testimony, the trial court found such testimony wanting: "He's not — right. His observations of 2,000 implants is clearly not going to pass a Robinson challenge. So I mean, it's just not. It's just not a scientific — it's just not a scientific test." (Bonnette Hearing Transcript at 55).

As the foregoing cases demonstrate, Dr. Blais' opinions are largely unsubstantiated, unscientific, overbroad and are the product of his extreme personal bias. Dr. Blais' proposed testimony in this case is inadmissible for a host of reasons.

## ARGUMENT

## THE TESTIMONY OF PIERRE BLAIS FAILS TO MEET THE RELIABILITY AND RELEVANCE REQUIREMENTS OF DAUBERT

Most of Dr. Blais' opinions go beyond his qualifications as a chemist, and none of them is supported by scientific testing. Dr. Blais' proposed testimony fails to satisfy any of the Daubert requirements and, therefore, should be excluded, as it has been in other recent cases.

### A. Dr. Blais Is Not Qualified to Testify About the Design or Manufacture of Breast Implants, Product Defects, Warnings or Medical Causation.

This Court need not reinvent the wheel when it comes to excluding Dr. Blais' testimony. The foregoing courts have thoroughly analyzed Blais' qualifications over the past decade and have found them lacking in the following areas:

- The design and manufacture of breast implants. Havard v. Baxter Int'l Inc.; In re: Breast Implant Litig.; Johnson v. Baxter Healthcare Corp..
- Product defects. Giddings v. Bristol-Myers Squibb Co; Grant v. Bristol-Myers Squibb; Johnson v. Baxter Healthcare Corn.
- Warnings. Havard v. Baxter Int'l Inc.; In re: Breast Implant Litig.
- Medical issues and causation. Giddings v. Bristol-Myers Squibb Co.; Pozefsky v. Baxter Healthcare Corp.; Havard v. Baxter Int'l Inc.; In re: Breast

Implant Litig.; Johnson v. Baxter Healthcare Corn.; Mining and Manufacturing Co. v. Atterbury; Clements v. 3M; Bailey v. Dow Corning Corporation; Bonnette v. Minnesota Mining and Manufacturing Company.

Dr. Blais is attempting to testify on the same general topics that other courts, acting as gatekeepers, have found him unqualified to testify about. There is no reason for this Court to be the exception to the rule. Dr. Blais should be held unqualified to testify on the proposed topics, including alleged design or manufacturing defects, warnings, medical issues or causation.

**B. Dr. Blais' Methodology Is Not Scientifically-Reliable.**

Plaintiffs cannot satisfy their burden of establishing that Dr. Blais' methodology is scientifically reliable because he has produced no data or work product that can be subject to peer review. His "methodology" essentially consists of looking at explanted breast implants, sometimes with the aid of a microscope, making a few notes and drawing pictures of what he claims to see. Without independent testing and validation, and without publication for the review and comment of his peers, Dr. Blais' methodology is nothing more than a subjective exercise. It does not provide a valid scientific basis to support his conclusions

regarding implant "defects" and thus fails to satisfy Daubert and Rule 702.[4]

Daubert's exacting standard also applies to "experience" based opinions, and thus, Dr. Blais' testimony is excludable for that independent reason. Carmichael v. Kuhmo Tire, Ltd., 526 U.S. 137 (1999).

Plaintiffs' counsel admitted in open Court:

> And, so, when we get the tox – the report from Dr. Blais and we talk to our – the explant doctor who appears to know what she's talking about, we believe that it's a relatively simple case in terms of here's what's in [the implant] and here's who can testify about it. . . . ***When they go in and take the deposition of Dr. Blais, it becomes clear that we may have some Daubert problems*** in terms of getting that in front of a jury, unless we have a pathologist like Dr. Shanklin to testify about what's in [the implants].
>
> * * *

[4] See Cook v. American Steamship Co., 53 F.3d 733, 739-40 (6th Cir. 1995) (holding that materials engineer's conclusion regarding the cause of rope breakage was not admissible expert opinion because it was based solely upon gross and microscopic examination of rope and not upon any testing or scientific knowledge); Diviero v. Uniroyal Goodrich Tire Co., 919 F.Supp. 1353,1359-60 (D. Ariz. 1996) aff'd, 114 F.3d 851 (9th Cir. 1997) (excluding materials expert's opinion regarding tire defect because expert had merely examined the tire, failed to eliminate alternative causes of failure, and relied on nothing other than his experience in examining tires to conclude there was a defect); Mitchell v. Uniroyal Goodrich Tire Co., 666 So.2d 727, 730-31 (La.Ct.App. 1995) (excluding engineering expert's opinion regarding cause of tire failure under Daubert where expert simply relied on observation and "old" literature, and conducted no independent testing); Arrendondo v. Uniroyal Goodrich Tire Co., 1995 U.S. Dist. Lexis 19943) (August 15, 1995) (excluding materials engineer's testimony because he relied exclusively on his experience in examining tires, had conducted no controlled studies on failure, and relied on no supporting scientific authority).

> Dr. Shanklin is – but he is an expert pathologist. He can put together – he can look at, do the tests that are outlined in his letter, and answer those questions in terms of eliminating other possibilities and honing down exactly what was in that implant, in all probability, and what injured Mrs. Lakey. And without Dr. Shanklin, we don't really have that link. ***We have a gap – we have what Daubert would call an analytical gap between A and B.***

Hearing Transcript, Aug. 1, 2006, relevant portions attached hereto as Exhibit O. The Court need not take Mentor's word for it. Plaintiffs have already admitted that they have a Daubert problem with Dr. Blais' testimony and that there is an analytical gap between his data and his (and Dr. Kolb's) conclusions.

**1. Dr. Blais' Theories Have Not Been Tested.**

The first Daubert factor is whether the theory "can be (and has been) tested." Daubert v. Merrell Dow Pharms., 509 U.S. 579, 593 (1993); Kelley v. American Heyer-Schulte Corp., 957 F.Supp. 873, 876 (W.D. Tex. 1997) ("[t]he hallmark of acceptable testimony [is] whether the scientific conclusion is testable and has been tested").

Judge Sparr's opinion excluding Dr. Blais' testimony in its entirety properly concludes that "Dr. Blais' hypotheses. . . have not been tested. . . . Neither Dr. Blais nor others have tested his theories." In Re Breast Implant Litigation, 11 F. Supp.2d at 1242. Those untested theories fail to pass muster under Daubert. His

test "methodology" consists of merely looking at an implant -- with or without the aid of a microscope and writing notes.

Blais admits that he conducted no testing to determine if Plaintiff's implants can leak in the manner he theorizes. (Blais Dep. at 141-42). He has conducted no testing or analysis of the material in Plaintiff's implants and cannot definitively say what it is. (Id. at 148-51, 157, 168-69). Without any scientific data to support his opinions, Blais's testimony is nothing more than speculation.

**2. Dr. Blais' Theories Have Not Been Peer-Reviewed.**

The second Daubert factor is "whether the theory or technique has been subjected to peer review [and/or] publication." Daubert, 509 U.S. at 593.

Judge Sparr observed that "Dr. Blais' theories . . . have not . . . been published in the peer reviewed literature. . . . No publication of Dr. Blais' hypotheses, methodology or opinions exists in the peer reviewed literature. Dr. Blais concedes that he does not publish." In Re Breast Implant Litigation, 11 F. Supp.2d at 1242-43.[5]

[5] Blais has attempted to claim that the reports he prepares for plaintiffs in breast implant litigation are "publications" peer-reviewed by defense experts. Obviously, Blais' definition is not what was meant in Daubert by publication and peer review. The litigation process is not a sufficient test of the validity of scientific propositions; "the examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or

That remains true in this case. Blais has not published any of his opinions on bacterial or fungal colonization of saline breast implants in peer-reviewed literature. (Blais Dep. at 174-75). He is the only one who has theorized that "faulty valves" could allow bacteria or fungus to enter an implant *in vivo* and "colonize" it. (Id. at 170-71). Not one peer-reviewed article suggests that microorganisms enter saline implants through faulty valves. (Id.).

Indeed, all of the peer-reviewed literature on this rare topic indicates that in the rare instances where bacterial or fungal contamination of saline implants is found, the contamination was from an external source, i.e., contaminated saline filling solution (which Mentor does not manufacture or provide), iatrogenic contamination, contaminated surgical instruments, contamination from the patient's body, etc.[6] (Id.). Even Blais agrees that microorganisms causing infection get into the body or implant by some type of external contamination and

(continued…)

medicine." Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985); Smelser v. Norfolk Southern Rlwy. Co., 105 F.3d 299, 305 (6th Cir. 1997).

[6] Brown, M. H., et al., "Microbial Growth in Saline Breast Implants and Saline Tissue Expanders," Plastic & Reconstructive Surgery (June 2002), attached hereto as Exhibit P; Becker, H. et al., "Do Saline Breast Implants Harbor Microbes?" Annals of Plastic Surgery, 36: 342 (1996) ("Unsubstantiated claims have been made by several investigators that saline implants are ideal culture media for bacteria and that the majority of saline implants harbor microbes. . . . [T]he complete negative findings support the evidence against problematic microbial contamination within saline implants."), attached hereto as Exhibit Q.

that Mentor's sterilization and manufacturing processes adequately prevent contamination. (Id. at 181-83). As Blais always claims, he has not attempted to publish any of his views because, as he always claims, the information is obvious; it would be insulting to his colleagues to publish it. (Id. at 174-76).

**3. Dr. Blais' Theories Have a High Rate of Error.**

The third Daubert factor is the technique's "known or potential rate of error." Daubert, 509 U.S. at 594. Judge Sparr, after carefully evaluating Dr. Blais' prior testimony and reports, declared that "Dr. Blais' opinions have either a high or an undetermined rate of error." In Re Breast Implant Litigation, 11 F. Supp.2d at 1243. Blais' theories have a large and unknown rate of error because they are completely subjective.

For example, Blais testified here that because he believed the valve cap measurements did not provide a secure-enough fit, the valve is, in effect, "an open hole." But Blais is entirely mistaken. The valve cap is not the "cork in the wine bottle" as Blais likes to analogize. (Blais Dep. at 86-87). The valve cap is a purely redundant safety measure designed to prevent tissue ingrowth into the valve. The actual diaphragm valve which prevents saline from leaking out, or bodily fluid from leaking in, lies under the valve cap. (Wyatt Aff. at ¶ 23, attached hereto as Exhibit R). Incredibly, Blais states that despite the fact that no one on the face of

the earth has observed the implants leaking, it is his opinion that the valve is an "open hole." (Blais Dep. at 142-43). Blais is completely wrong on his main theory of valve defect which he has held for decades.

**4. Dr. Blais' Theories Have Not Been Generally Accepted by the Scientific Community.**

The fourth Daubert factor is whether the underlying theory or technique has been generally accepted as valid by the relevant scientific community. Daubert, 509 U.S. at 594. The Court in Daubert stated that "[w]idespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." Id. (citation omitted).

Dr. Blais's theories are not accepted by any scientist other than Dr. Blais, a fact he readily acknowledges and attributes to lack of interest among his colleagues. As discussed supra, no other scientists have published studies that support, or even address, Dr. Blais's theories. They are uniquely his. Even the FDA disagrees with Blais. In 2000, the FDA granted Mentor's saline breast implants pre-market approval, meaning that the FDA found the implants to be "safe and effective." (Wyatt Aff. at ¶ 4; Ex. B & C). By definition, therefore, Dr. Blais's reasoning and ideas cannot be "generally accepted."

In fact, the peer-reviewed literature on this topic unanimously demonstrates that Blais is wrong. As recognized by numerous courts, experts whose theories inexplicably conflict with those of their peers have no scientific basis and their opinions should not be accepted.[7]

The opinions which Dr. Blais offers fail not only to be "generally accepted" science; quite often, they fail even to be reasonably acceptable as "science" at all.

**5. Dr. Blais' Opinions Were Not Developed Independent of Litigation.**

The final Daubert factor relates to the non-judicial uses which have been made of the theory or technique. "One very significant fact to be considered [in deciding whether to admit expert testimony] is whether the experts are proposing to testify about matters growing naturally and directly out of research they have

[7] See Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1360 (6th Cir.), cert. denied, 506 U.S. 826 (1992) (finding no scientific basis for testimony of causation expert who did "not testify on the basis of the collective view of his scientific discipline, nor . . . [took] issue with his peers and explain[ed] the grounds for his difference") (emphasis added) (cited in Hall v. Baxter Health Care, 947 F.Supp. 1387, 1406 (D. Or. 1996)); O'Connor v. Commonwealth Edison Co., 807 F.Supp. 1376, 1398 (D. Ill. 1992) ("[A]n expert opinion that *actually contradicts directly* the scientific consensus is inadmissible.") (emphasis in original), aff'd, 13 F. 3d 1090 (7th Cir.), cert., 512 U.S. 1222 (1994) (cited in Hall, 947 F.Supp. at 1406); Conde v. Velsicol Chem. Comp., 804 F.Supp. 972, 1024 (S.D. Ohio 1992) ("[W]hen an expert expresses an opinion which is not generally accepted within the medical and scientific communities, he has an obligation to provide a reasoned explanation of why his methodology and opinions differ."), aff'd, 24 F.3d 809 (6th Cir. 1994) (cited in Hall, 947 F.Supp. at 1406).

conducted independent of litigation, or whether they have developed their opinions expressly for purposes of testifying." Daubert v. Merrell Dow Pharms., 43 F.3d 1311 (9th Cir. 1995); Smelser, 105 F.3d at 303. This factor is particularly relevant in the case of Dr. Blais, and casts a powerful, if somewhat unflattering, light on his work.

As Judge Sparr concluded, "Dr. Blais' opinions are not developed independently of litigation. In fact, the vast majority of Innoval's business comes from plaintiffs involved in breast implant litigation. . . . This factor provides an additional reason for excluding Dr. Blais' testimony here." In Re Breast Implant Litigation, 11 F. Supp.2d at 1243.

In mid-1995, and consistently throughout the 90's and early 2000's, Blais testified that 60-70% of Innoval's business was product failure analysis and forensic studies (Merlin Deposition Transcript at 42, relevant excerpts attached hereto as Exhibit S); very close to 100% of that was related to breast implants (Merlin Deposition Transcript at 45), and 95% of that is for plaintiffs. (Merlin Deposition Transcript at 46).

In addition, as noted in Wilson v. Guichon, the court found his testimony so unreliable and so obviously biased that it was rejected. (Wilson Order at 34).

Blais' opinions were developed purely for litigation, a "very significant fact." Daubert, 43 F.3d at 1317. He is a "professional plaintiffs witness." Lust v. Merrell Dow Pharms., Inc., 89 F.3d 594, 597 (9th Cir. 1996). For his opinion to be admissible in a federal court he must explain "how he went about reaching his conclusions" and point "to an objective source demonstrating that his method and premises" are generally accepted by at least a minority of scientists in the field. Id. This he cannot do.

Moreover, prior testimony and consulting work for litigation does not qualify a person as an expert. See Stokes v. Geismar, S.A., 815 F.Supp. 904, 909 (E.D. Va. 1993) ("[t]he Court is mindful of the ease with which parties can procure so-called experts nowadays to endorse almost any theory of a case"), aff'd, 16 F.3d 411(4th Cir. 1994); Van Blargan v. Williams Hospitality Corp., 754 F.Supp. 246, 249 (D.P.R. 1991) ("such a practice in effect makes the proposed witness an expert only for the party which employs him, rather than an objective expert witness"). Indeed, the fact that Blais has an agenda renders his opinions even less credible.

**C. Blais' Testimony Is Not Relevant.**

Dr. Blais' qualifications are extremely narrow. He is a chemist. The testimony he could provide in this case would not be relevant to Plaintiff's claims for negligence and intentional infliction of emotional distress. In fact, Blais has

even stated he is not testifying that Mentor was negligent or reckless or that Mentor intentionally tried to harm Plaintiff. (Blais Dep. at 252-53). Nothing Dr. Blais says would be admissible in this case.

## CONCLUSION

For all of these reasons, Mentor requests that the Court exclude the testimony of Dr. Blais, as other courts have.

Dated: September 1, 2006

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT**
**IN AND FOR THE NORTHERN DISTRICT OF GEORGIA**

| | |
|---|---|
| ELIZABETH A. LAKEY, et al.,<br><br>Plaintiffs,<br><br>v.<br><br>MENTOR CORPORATION,<br><br>Defendant. | Civil Action No. 1:05-CV-0929-TCB |

## LOCAL RULE 7.1(D) CERTIFICATION

Pursuant to Local Rule 7.1(D), I hereby certify that this brief has been prepared with Times New Roman, 14-point font.

/s/ Dustin B. Rawlin
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*Pro hac vice*
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**MENTOR CORPORATION**

**IN THE UNITED STATES DISTRICT COURT**
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## CERTIFICATE OF SERVICE

I hereby certify that, on September 1, 2006, I electronically filed Defendant Mentor Corporation's Motion to Exclude the Testimony of Pierre Blais, Ph.D. and Memorandum in Support using the CM/ECF system which will automatically send email notification of such filing to the following attorneys of record:

Frances L. Spinelli
Roger C. Wilson

Respectfully submitted this 1st day of September, 2006.

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